Reg. No.										

Manipal Institute of Technology, Manipal

(A Constituent Institute of Manipal University)

II SEMESTER M.TECH (INDUSTRIAL BIOTECHNOLOGY)

END SEMESTER EXAMINATIONS, MAY 2016 / JUNE 2016

SUBJECT: Biopharmaceutical & Pharmaceutical Biotechnology [BIO 524]

REVISED CREDIT SYSTEM

Time: 3 Hours MAX. MARKS: 50

Instructions to Candidates:

- Answer **ANY FIVE FULL** the questions.
- Missing data may be suitable assumed.

1A	What are the uses of pharmacokinetic models?	**3**
1B	Explain physiological pharmacokinetic model with a neat flow diagram?	**3**
1C	What are the different theories available to explain the structure of cell membrane and explain it briefly?	**4**
2A	Explain the pH – partition hypothesis for the movement of drug molecules across the cell membrane.	**3**
2B	Given the following data, collected after a 300 mg i.v. bolus dose, calculate k, Cp_0, V_d, $t_{1/2}$, and AUC (using the trapezoidal rule). Time (hr): 1, 2, 6, 12 Concentration (mg/L): 15.7, 13.8, 8.3, 3.2	**5**
2C	What are the advantages and disadvantages of subcutaneous route of administration of drug	**2**
3A	Derive the mathematical expression to determine apparent volume of distribution using area under curve. Assume drug follows one compartment and administrated via IV Bolus route	**4**
3B	A single IV dose of an antibiotic was given to a 50-kg woman at a dose level of 20 mg/kg. Urine samples were removed periodically and assayed for parent drug. The following data were obtained: Time (hr): 0.25, 0.5, 1, 2, 4, 6 D_u (mg): 160, 140, 200, 250, 188, 46 Calculate elimination rate constant and half-life period of drug using rate method	**4**
3C	What is the significance of apparent volume of distribution?	**2**
4A	100 mg of a drug was administered by rapid IV injection to a 70-kg, healthy adult male. Blood samples were taken periodically after the administration of drug, and the plasma fraction of each sample was assayed for drug. The following data were obtained: Time (hr): 0.25, 0.5, 1, 1.5, 2, 4, 8, 12, 16 Plasma Concentration (µg/mL): 43, 32, 20, 14, 11, 6.5, 2.8, 1.2, 0.52 Calculate rate constants of two compartment model	**5**

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4B	An antibiotic has an elimination half-life of 4 hours in the general population. A patient was given an IV infusion of an antibiotic at an infusion rate of 15 mg/hr. Blood samples were taken at 8 and at 24 hours and plasma drug concentrations were 5.5 and 6.5 mg/L, respectively. Estimate the elimination half-life of the drug in this patient.	**3**
4C	A physician wants to administer an anaesthetic agent at a rate of 2 mg/hr by IV infusion. The elimination rate constant is 0.1 hr^{-1}, and the volume of distribution (one compartment) is 10 L. What loading dose should be recommended if the doctor wants the drug level to reach 2µ g/mL immediately?	**2**
5A	Two drugs, A and B, have the following pharmacokinetic parameters after a single oral dose of 500 mg: Drug | k_a (hr^{-1}) | k (hr^{-1}) | V_D (mL) A | 1.0 | 0.2 | 10,000 B | 0.2 | 1.0 | 20,000 Both drugs follow a one-compartment pharmacokinetic model and are 100% bioavailable. Calculate the t_{max} and C_{max} for each drug	**4**
5B	Is clearance a better parameter to describe drug elimination than half-life? Why is it necessary to use both parameters in the literature?	**2**
5C	Develop the mathematical expression to predict the plasma drug concentration when the drug is given to the patient by IV infusion (Assume drug is eliminating by first order and follows one compartment model)	**4**
6A	Explain different steps involved in hard capsule manufacturing process?	**4**
6B	Discuss the different steps involved in wet granulation process & dry granulation process.	**4**
6C	Explain the working principle of roller compaction?	**2**